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FAX TRANSMISSION

DATE: March 14, 2005

TO: Commissioner for Patents
Attn: Examiner M. DeSanto
Mail Stop Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

FROM: David M. Crompton

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Ting Tina Ye et al.	Confirmation No.:	2367
Serial No.:	09/839,065	Examiner:	M. DeSanto
Filing Date:	April 20, 2001	Group Art Unit:	3763
Docket No.:	1001.1471101	Customer No.:	28075
For:	MICROCATHETER WITH IMPROVED DISTAL TIP AND TRANSITIONS		

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REPLY BRIEF UNDER 37 C.F.R. § 41.41

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Dear Sir:

Pursuant to 37 C.F.R. § 41.41, Appellant hereby submits this Reply Brief in response to the Examiner's Answer mailed on January 14, 2005. Remarks begin on page 2.

REMARKS

1. General Comments

Appellants agree with the Examiner's statements in paragraphs 1-6 of the Examiner's Answer.

In paragraph 7 of the Examiner's answer, it is stated that claims 1, 3-34, and 41 stand or fall together because the brief did not include a statement regarding grouping of the claims. Appellants traverse this statement. The relevant regulations changed effective September 13, 2004, prior to the date of the Appeal Brief. As noted in the Federal Register, in the comments accompanying the final rule, "The grouping of claims requirement set forth in former rule 192(c)(7) is removed." (Federal Register, Vol. 69, No. 155, at p. 49,962). Therefore the claims do not stand or fall together, as a statement to that effect is no longer required due to the change in the Board Rules. By arguing the claims separately, Appellants have assured that the claims do not stand or fall together.

Appellants agree with the Examiner's statements in paragraphs 8-10 of the Examiner's Answer.

Appellants traverse the statements made in paragraph 11 of the Examiner's answer variously for reasons given in the Appeal Brief as well as for reasons further discussed herein.

2. Comments With Respect to the Previous Reasons for Rejection

It appears at this stage of the proceedings that the main disagreement is whether the claims are subject to a "product by process" interpretation. Appellants are uncertain of the Examiner's position in light of the following statement, appearing on page 3 of the Examiner's Answer:

> The applicant argues that the examiner has interpreted "shapeable by thermoforming techniques" as a product by process claim recitation. This is not true. The Examiner is interpreting that statement as a product by process limitation and has given that limitation the full scope as suggested by the MPEP, in sections 2112.01, 2112.02, and 2113.

It appears from the rest of the document that the Appellants are correct in stating that the Examiner has interpreted "shapeable by thermoforming techniques" as a product-by-process claim recitation, in contrast to the first sentence in the above quoted passage. This understanding is supported, for example, by the third sentence in the above-quoted passage. Further, the Examiner has repeatedly stated the same, for example, in the November 4, 2004 Advisory Action, on page 2 ("The examiner stated those cases as support to his interpretation of the product by process limitation"). This understanding is also supported at paragraph 6, on page 5, of the January 28, 2004 Office Action ("... the examiner holds the limitation 'shapeable by thermoforming techniques' to be a product by process limitation"), and paragraph 6, on page 5, of the August 12, 2003 Office Action ("... this limitation is a product by process limitation").

In the paragraph extending from page 3 onto page 4 of the Examiner's answer, it is stated that MPEP 2173.05(p)(I) "does not given an insight into how to interpret claims that have process limitations in an apparatus claim. Sections 2112.01, 2112.02, and 2113 of the MPEP are the areas that cover the interpretation of these claims." It appears the point has been missed: Appellants have stated repeatedly that the claims are not product by process claims. MPEP 2173.05(p)(I) gives an insight as to whether a claim should be treated as a product by process claim, since this section defines what is a "product by process" claim. Thus the dismissal of this section of the MPEP, as "providing no insight," appears incorrect.

As an example, a product by process claim could recite "a catheter shaped by thermoforming techniques." Appellants believe such would be a product by process recitation,

since a specific step of fabrication is recited. However, "shaped by" is not the same as "shapeable by". These are quite different requirements.

The Examiner cites sections 2112.01 (Composition, Product and Apparatus Claims) as well as 2112.02 (Process Claims), both of which fall within MPEP 2112, which is the MPEP section for Inherency Rejections. Each of these sections were cited for the first time in the present prosecution in the Advisory Action dated November 4, 2004, and repeated in the Examiner's Answer. Thus, it appears that the Examiner is now attempting to change the grounds of rejection by bringing into consideration the question of whether there is inherent disclosure in the cited references.

The Examiner also cites MPEP 2113, which is a section dealing with how a product-by-process claim should be interpreted. However, this section is not appropriate to the instant appeal insofar as the question is not how a product-by-process claim should be interpreted, but instead, whether the present claims are product-by-process claims. It is believed that this portion of the Examiner's argument is adequately addressed in the Appeal Brief, as supplemented by the above remarks.

In the first full paragraph on page 4 of the Examiner's Answer, it is stated that the term "shapeable" does not give structure to the claimed device. The word "shapeable" should be understood as meaning "capable of being shaped". Thus, it is a material property of a portion of the recited device. When read in light of the specification, it is apparent that "shapeable" indicates that the material of a section of the device is capable of being shaped and holding the new shape in place of an earlier shape. One example would be that a catheter in accordance with the claim may have a section having the material property that it holds a first shape at a first time

and, later, for example after treatment such as thermoforming, it can be reshaped into a different shape, which it will hold thereafter. The Examiner states:

> The examiner agrees that the term shapeable means that the tip has the ability to be shaped, which is what the prior art reference discloses throughout the background and specification (see Sampson, column 1, lines 20-25).

However, the cited section of Sampson merely states the following:

> In particular, catheters which use the circulatory system as the pathway to these treatment sites are especially useful. For instance, it is commonplace to treat diseases of the circulatory system via angioplasty (PTA) using catheters having balloons at their distal tips.

(Sampson et al. at column 1, lines 20-25). Appellants are at a loss to respond to this statement and reference. At the very least, Appellants see no discussion or disclosure in the cited passage that can correspond to that which the Examiner is apparently suggesting.

The Examiner also cites to pages 5-6 of the February 25, 2003 Office Action. There, the Examiner had explained that the term "shapeable" was being interpreted as indicating that the catheter had sufficient flexibility to enter into a patient and navigate the blood vessels thereof. However, claim 1 recites, in part:

> a second layer disposed over the inner liner, the second layer including a first segment and a second segment, the first segment extending to a distal terminus and the second segment extending from the distal terminus to a radiopaque marker band disposed proximal of the distal end of the shaft, wherein the distal terminus is set back from the distal end of the shaft a distance equal to or greater than the shapable length;

If the Examiner is interpreting the portion of the catheter of Sampson that is shapeable as being the portion that is sufficiently flexible to enter the patient, then it appears Sampson et al. does not disclose a catheter as recited. In particular, it is rather improbable that there could be the recited first and second layers, as the first segment must terminate proximal of the flexible portion of the catheter. Since the flexible portion of the catheter, as interpreted by the Examiner, includes all of

the catheter that enters the patient, there is no second layer having the recited first segment disclosed by Sampson. Thus, even using the Examiner's interpretation of "shapeable", Sampson et al. provides no corresponding structure for the rest of the claim.

The paragraph extending from the bottom of page 4 onto page 5 and the first full paragraph on page 5 of the Examiner's Answer are separately addressed below in accordance with Appellants' understanding of the language therein.

Appellants now turn to the discussion in the paragraph extending from page 5 to page 6 and the first full paragraph on page 6. The Examiner cites three passages from Sampson et al. in this portion of the Examiner's Answer. With respect to the cited passages, the passages in column 6 of Sampson et al. discuss heat shrinkable tubular elements. However, a heat shrinkable tube would not be considered a "shapeable length", as the term "heat shrinking" with respect to the tube is understood as indicating a reduction in the size of the tube, rather than a change in the shape thereof. The passage in column 7 discusses annealing a tubular braided member. However, the step of annealing is performed to relieve stresses within a formed piece, rather than to re-shape the piece. Annealing by definition does not cause reshaping of the piece. Further, none of these sections discuss an assembled, completed catheter, but instead describe individual components. The second full paragraph on page 6 merely restates the same disagreement as noted above, and provides the Examiner's conclusion which, for the reasons already stated, Appellants traverse.

With respect to the discussion in the second full paragraph on page 6 of the Examiner's Answer, the Examiner is correct that Appellants have addressed whether Nita et al. can supplement Sampson et al. to form a proper §103 rejection. This discussion included showing that Nita et al. do not show a shapeable length and/or catheter as recited. The Examiner appears

to be agreeing with Appellants that, if Sampson et al. do not provide adequate basis for the other stated rejections, then reference to Nita et al. is inapposite.

Finally, with respect to the discussion in the second paragraph on page 6 of the Examiner's Answer, Appellants agree, and have not found nor stated a reason to question the modification of either reference. Instead, Appellants disagree with respect to the application of the claim language to the references and the interpretations given to the claim language.

3. Comments with Respect to the New Rejection Explanation

In the paragraph extending from page 4 onto page 5 of the Examiner's Answer, the following sentence appears: "In claim 1, 'the distal tip having a shapeable length that is shapeable by thermoforming techniques', is being interpreted as a functional statement, with a product by process limitation." This is a new approach to these rejections from that stated before. It appears that the material property term, "shapeable length" is to be treated as merely functional (it is unclear what the function is), while the modifier of that material property, "by thermoforming techniques", is treated as a product by process limitation. Appellants appreciate the specific nature of the explanation of the rejection. While the approach is new, it is believed that the rejection is not new, as it relies upon the same references as before.

In considering a rejection, it is necessary to consider the entire claim. While this new explanation provides a clearer understanding of the rejection, it also places the rejection squarely within the bounds of the reasoning stated above. Specifically, the claims recite a second layer over the inner liner, with the second layer having sections including a section ending at a distal terminus, wherein the shapeable length or portion is entirely distal of the distal terminus. No such sections are included in the catheter as shown by Sampson et al. Particularly, the recited

proximal section of the second layer would have to terminate proximal of the portion of the Sampson et al. catheter that is used for entering a patient. This is so because, by the Examiner's interpretation, the "shapeable length" is the portion of the Sampson et al. catheter that is sufficiently flexible to enter the patient and traverse the vasculature therein. Sampson et al. do not provide explanation of any layered structures of the proximal end of the catheter disclosed therein. Thus, the required disclosure is lacking.

When considering the claim language in its submitted form, of course, the phrase "shapeable by thermoforming techniques" is not amenable to the broad definition given to "shapeable" used by the Examiner, as the overall term provides an additional limitation, that a portion of the catheter, and not just disassembled components thereof, is shapeable by thermoforming techniques.

The new explanation of the rejection, including a specific parsing out of claim limitations as discussed by the Examiner, still fails to establish a *prima facie* case of unpatentability. In light thereof, reversal of all pending rejections is respectfully requested.

Respectfully submitted,
Ting Tina Ye et al.
By their attorney,

Date: 3/14/05

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